IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION **This document relates to:** ***Track One Cases***	**MDL No. 2804** **Case No. 17-md-2804** **Hon. Dan Aaron Polster**

REPLY BRIEF IN SUPPORT OF TEVA AND ACTAVIS GENERIC DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. ARGUMENT 2

A. All False Marketing Claims Against Moving Defendants Fail 2

1. There Is No Evidence That Moving Defendants Engaged In Any False Marketing In Ohio 2

2. Plaintiffs Cannot Rely On Third Party Statements To Support Their False Marketing Claims 6

3. Plaintiffs Fail To Establish The Element Of Causation 7

4. Plaintiffs Have Not Shown A Cognizable Injury Linked To Moving Defendants' Medicines 8

B. The SOM Claims Fail For Lack Of Evidence As To The Key Elements 8

C. Plaintiffs Cannot Meet Their Burden Because They Have Chosen Not To Present Evidence Against Most Of Moving Defendants 9

D. All Claims Are Barred By The Applicable Statute Of Limitations 10

TABLE OF AUTHORITIES

Page(s)

Cases

BMW of N. Am., Inc. v. Gore,
517 U.S. 559 (1996).....5

Brown v. Fred's, Inc.,
494 F.3d 736 (8th Cir. 2007).....10

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001).....3, 5

Carpenters Welfare Fund v. *Cephalon, Inc.*,
No. 13-7167, 2014 WL 2115498 (E.D. Pa. May 21, 2014).....3, 5

Everson v. Leis,
556 F.3d 484 (6th Cir. 2009).....8

Healy v. Beer Inst., Inc.,
491 U.S. 324 (1989).....5

McWilliams v. S.E., Inc.,
581 F. Supp. 2d 885 (N.D. Ohio 2008).....6

Pang v. Minch,
559 N.E.2d 1313 (Ohio 1990).....7, 10

Rugiero v. Nationstar Mortg., LLC,
580 F. App'x 376 (6th Cir. 2014).....8

Sindelir v. R.J. Corman Const.,
No. 93-3042, 1993 WL 533119 (6th Cir. Dec. 23, 1993).....7, 10

Solis v. Milling Away, LLC,
No. 5:09CV2886, 2012 WL 359688 (N.D. Ohio Feb. 2, 2012).....3

Sorrell v. IMS Health Inc.,
564 U.S. 552 (2011).....4

Taylor v. Checkrite, Ltd.,
627 F. Supp. 415 (S.D. Ohio. 1986).....6

United States v. Caronia,
703 F.3d 149 (2d Cir. 2012).....3

Zappola v. Hennig,
20 F. Supp. 2d 1150 (N.D. Ohio 1998).....8

Zappola v. Henning,
201 F.3d 442 (6th Cir. 1999) 8

Other Authorities

21 C.F.R. § 1301.74(b) 9

Fed. R. Civ. P. 408.....3

I. INTRODUCTION

Plaintiffs concede that they must "prove their claims against ***each individual defendant*** based upon ***each defendant's*** alleged wrongdoing."[1] It is now clear they cannot satisfy that burden with respect to Moving Defendants.[2] Summary judgment should be entered.

First, Plaintiffs fail to present evidence sufficient to prove the core elements of their false marketing claim. They have not identified any: (1) false statement by Moving Defendants to a doctor in Summit or Cuyahoga County (the "Counties"); that (2) caused that doctor to write an inappropriate prescription; that (3) led the patient to become addicted, overdose, or suffer some injury; which (4) led to financial harm to the Counties or conditions constituting a public nuisance.

Plaintiffs do not attempt to address each element. The undisputed record shows why. Teva USA and the Actavis Generic Defendants sold generic medicines. They did not promote them, nor make representations about their safety or efficacy. As generic manufacturers, they could provide no information beyond the product label. Thus, they sold based on price and availability, within the limits set by DEA quotas. There is nothing fraudulent about such conduct.

As to branded products, Cephalon and Teva USA only ever sold two short-acting opioids (Actiq and Fentora) indicated for the treatment of breakthrough cancer pain. There is no evidence that Cephalon promoted these medicines to treat chronic pain or some condition other than the approved indication in any County—yet, even if that were the case, "off-label" promotion is not inherently false. That is particularly true here, where the undisputed evidence shows that Actiq and Fentora can be effective in treating non-cancer breakthrough pain—an "off-label" use. Put simply, Plaintiffs do not identify a single false statement made about any of these medicines in

[1] Pls.' Mot. to Sever, ECF No. 2099, at 2.

[2] "Moving Defendants" are Cephalon, Inc. ("Cephalon"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), and the "Actavis Generic Defendants," which include eleven distinct corporate entities, as explained in Moving Defendants' opening memorandum.

either County. They also ignore that, since March 2012 (*i.e.*, throughout the limitation period), prescribing doctors, patients, pharmacists, and distributors all have been legally obligated to acknowledge in writing the risks associated with those medicine—a TIRF REMS Program requirement. While Plaintiffs try to escape this undisputed evidence by pointing to the statements of third parties, they offer no evidence that any Moving Defendant controlled or influenced those third parties, and the undisputed evidence is that they did not. There is nothing unlawful about a company providing financial support to third-party organizations that independently advocate for pain treatment. To the contrary, that is constitutionally-protected speech.

Second, Plaintiffs cannot proceed with their claims premised on alleged deficiencies in Moving Defendants' safeguards against diversion. Plaintiffs wrongly assert, based upon a misreading of the law and heightened standards imagined by their experts, that Moving Defendants' suspicious-order monitoring ("SOM") systems were inadequate. But even if those systems were inadequate, summary judgment still would be required because Plaintiffs have failed to present any evidence that Moving Defendants filled a single suspicious order in the Counties (or anywhere else). This glaring lack of proof precludes, as a matter of law and simple logic, the finding that any harm was caused by Moving Defendants' supposedly-inadequate SOM systems.

Lastly, Plaintiffs fail to introduce any evidence at all as to most of the fourteen Teva-affiliated companies Plaintiffs chose to sue, including Teva Ltd. This lack of evidence as to "each individual Defendant" absolutely requires summary judgment as to those Defendants.

II. ARGUMENT

A. All False Marketing Claims Against Moving Defendants Fail.

1. There Is No Evidence That Moving Defendants Engaged In Any False Marketing In Ohio.

Plaintiffs do not provide evidence of a single statement made by Cephalon, Teva USA, or

any other Moving Defendant to any doctor in either Summit or Cuyahoga County—much less a false statement. Not one. Instead, the undisputed evidence is that there was none.[3]

Plaintiffs cite repeatedly to a 2008 misdemeanor plea for off-label promotion by Cephalon involving Actiq and other non-opioid products (but not Fentora). (Opp. at 2, 6–7.)[4] In doing so, they attempt a sleight of hand—seeking to leave the impression that Cephalon pleaded guilty to fraudulent promotion from 2001 to 2006. But the conduct to which Cephalon pleaded guilty was limited to a 10-month period in 2001—more than a decade before the limitations period.[5] Indeed, Cephalon ceased promoting Actiq in 2006 and did not obtain approval for Fentora until 2006—well after the period at issue in the plea agreement. (Mem. at 5.) And even more critically, that nearly 20-year-old conduct did not involve fraudulent promotion. It involved the off-label promotion, which is a violation of FDA regulations but is not the same as fraud.[6] As a matter of law, off-label promotion is not inherently "false or misleading." *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012), and off-label prescribing is entirely legal.[7] It is undisputed that Actiq (and Fentora) can provide effective pain relief for patients suffering from the devastating effects of non-cancer breakthrough pain (an off-label use).[8] (Mem. at 9.)

Plaintiffs next assert that fraudulent marketing occurred in Ohio—but offer no evidence to back that up. (Opp. at 9.) Plaintiffs cite the testimony of Laura Sippial, a former Ohio sales

---

[3] Mov. Defs.' Mem. ISO MSJ ("Mem.") Ex. 54, ¶ 5 (no reports of improper marketing or promotion in Ohio); Ex. 1, V. Baldassano Dep. Responses, ¶ 153 (same).

[4] Plaintiffs also improperly reference a 2008 civil settlement involving Cephalon, along with a press release about that settlement. (Opp. at 6.) Apart from showing that Plaintiffs' claims are time-barred, the settlement agreement is irrelevant and not admissible to prove liability. *See* Fed. R. Civ. P. 408 (barring use of settlement for this purpose); *Solis v. Milling Away, LLC,* No. 5:09CV2886, 2012 WL 359688, at *6 (N.D. Ohio Feb. 2, 2012) (same).

[5] Mem. Ex. 59, Guilty Plea, ¶ 1.

[6] Ex. 1, V. Baldassano Dep. Responses, ¶ 36.

[7] In fact, off-label prescribing and use "often is essential to giving patients optimal care." *See, e.g.*, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 n.5 (2001); *see also Carpenters Welfare Fund* v. *Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *7 (E.D. Pa. May 21, 2014) (recognizing principle as to Fentora).

[8] M. Rosenblatt Report, ECF No. 1936-31, ¶¶ 37–52; E. Michna Report, ECF No. 1936-25, ¶ 35; R. Portenoy Dep., ECF No. 1983-8, 538:9–19; L. Webster Dep., ECF No. 1985-15 at 288:7–16.

representative for Cephalon, but the testimony makes clear there was no false marketing. Ms. Sippial received mandatory compliance training each quarter, during which she was instructed that she could only promote Cephalon's medicines for labeled indications, and that off-label promotion was illegal.[9] Plaintiffs make the irrelevant assertion that she "called on doctors with specialties other than oncology or pain specialists." (Opp. at 9.) But the FDA has long recognized that doctors other than oncologists and pain specialists can appropriately prescribe Actiq and Fentora.[10] And Plaintiffs fail to present any evidence that Ms. Sippial made a false or misleading statement to any doctor, regardless of specialty.[11]

Plaintiffs also argue that Cephalon made "20,000 sales calls relating to Fentora in Ohio" between 2006 and 2015 and speculate that it must have engaged in "inappropriate conduct" during those visits. (Opp. at 15.) However, there is nothing wrong with a pharmaceutical company promoting its products. That is constitutionally-protected conduct.[12] Plaintiffs offer no basis to conclude that the level of sales call activity was itself inappropriate. And Plaintiffs do not identify a ***single*** sales call during which something false or misleading was said. In fact, the testimony Plaintiffs cite confirms the opposite. Valerie Kaisen, a Cephalon sales representative for Ohio, testified that she never promoted Actiq or Fentora for off-label use (much less fraudulently), was never told to do so, and never used off-label promotional materials.[13] In short, there is no evidence

[9] L. Sippial Dep. ECF No. 2177-4, 354:1–356:24, 358:8–11, 360:16–361:1.

[10] The FDA has explained that TIRF medicines are prescribed by "anesthesiologists," "physical medicine and rehabilitation physicians," "primary care physicians," and other appropriately licensed "healthcare professionals." Mem. Ex. 10, TIRF REMS, at p. 6 § II(B)(1)(d)(vi). Even the Actiq Risk Management Program recognized that there would be off-label prescribing of Actiq by different medical professionals. Opp. Ex. 26, Teva_MDL_A_03272114, ¶ 9.1.2 (recognizing potential for "off-label usage greater than 15% of total quarterly *Actiq* prescriptions").

[11] L. Sippial Dep., ECF No. 2177-4, at 360:15–361:1.

[12] *See, e.g.*, *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 557 (2011) ("[s]peech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment").

[13] V. Kaisen Dep., ECF No. 2173-34, 272:23–273:12.

of false marketing by Cephalon in either of the Counties.[14]

Plaintiffs also cite a Fentora training guide and various marketing plans as evidence that Cephalon was aware that doctors prescribed Actiq and Fentora for non-cancer pain. (*Id.* at 12.)[15] But Plaintiffs do not link this evidence to any false marketing in Ohio. Off-label ***prescribing*** by a physician is an entirely ***legal*** activity;[16] it does not prove off-label ***promotion***—much less fraud. Plaintiffs also ignore Cephalon's strict internal policies prohibiting such conduct, the unrebutted testimony of Cephalon's sales representatives, and Cephalon's Corporate Integrity Agreement, which required Cephalon to monitor for and report any improper promotion of Cephalon's medicines to the Office of Inspector General.[17] There were no such reportable incidents related to Actiq or Fentora,[18] as confirmed by the unrebutted testimony of Cephalon's former Chief Compliance Officer—a former health care fraud federal prosecutor.[19]

Plaintiffs further cite a 2009 FDA letter to Cephalon about sponsored links to a Fentora website, but that letter merely explained that those links did not include Fentora's full indication and risks (which have always been fully disclosed in the label).[20] The letter did not suggest any improper detailing or any false marketing. There is no such evidence.

Lastly, Plaintiffs go so far as to argue that the Teva Defendants acted fraudulently by

---

[14] Any effort to base state law claims based upon conduct outside of Ohio would violate the Due Process and Commerce Clauses of the United States Constitution. *See, e.g., Healy v. Beer Inst., Inc*., 491 U.S. 324, 336 (1989) (Commerce Clause "precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within the State"); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572–73 (1996) (same). In any event, Plaintiffs do not have any evidence of fraud outside of Ohio either.

[15] Plaintiffs also mischaracterize a 2003 audit (again, prior to any applicable limitations period) of Cephalon's RiskMAP for Actiq. This 2003 internal audit addresses compliance with "commitments" to the FDA "communicated in the Risk Management Program dated August 1, 2001[.]" Opp. Ex. 47, TEVA_MDL_A_01159577. It has nothing to do with any false marketing, much less any in Ohio.

[16] *See Buckman Co.*, 531 U.S. at 351 n.5; *Carpenters Welfare Fund*, 2014 WL 2115498, at *7.

[17] Mem. Ex. 20, Cephalon Corporate Integrity Agreement, p. 22 (2008).

[18] *See* H. Dorfman Report, ECF No. 1936-11 at 39.

[19] Ex. 1, V. Baldassano Dep. Responses, ¶¶ 48, 67, 91, 94, 105–08.

[20] Opp. Ex. 82, TEVA_MDL_A_04183493–04183497. The Fentora link states "www.FENTORA.com Learn more about treating breakthrough pain in patients with cancer."

creating a video called "Pain Matters" (Opp. at 14–15), which sought to educate the public on the devastating effects of living with pain. Plaintiffs complain that the video stated that "chronic pain can impact more than 100 million Americans" and that a doctor appearing on the video discussed a published article on opioid addiction. (*Id.*) But these statements are not false;[21] to the contrary (as set forth in Appendix A), the video emphasized the crisis of "prescription opioid abuse," highlighted the risks of opioid "abuse, misuse, and diversion," and advocated a "multifaceted approach" to pain treatment.[22] Nor do Plaintiffs provide any evidence that any Ohio doctor relied upon any purportedly misleading statements in this video.

2. Plaintiffs Cannot Rely On Third Party Statements To Support Their False Marketing Claims.

Invoking the pejorative and misleading phrase "front groups," Plaintiffs contend that the Teva Defendants engaged in false unbranded marketing through organizations such as the American Pain Foundation ("APF"). (Opp. at 3, 14.) But Plaintiffs do not provide a shred of evidence showing that the Teva Defendants controlled such third-party organizations or their publications. Such control is required as a matter of law in order to impose liability on the Teva Defendants for the speech of third parties.[23] The undisputed evidence, including the actual grant agreements for the publications at issue, shows that the Teva Defendants had no such control.[24]

---

[21] The National Institute of Medicine previously found that "chronic pain conditions affect approximately 100 million U.S. adults." Ex. 2 at 302, 310, 313. Likewise, the doctor on the video accurately described the results of a 2008 literature review by David Fishbain. *Pain Medicine* Vol. 9, No. 4 (2007), Ex. 3 at 444 (cited in M. Rosenblatt Report at 39 n. 113).

[22] Opp. Ex. 109 at 4–5.

[23] *See McWilliams v. S.E., Inc.*, 581 F. Supp. 2d 885, 893 (N.D. Ohio 2008) (defendant not liable for third-party statements because no evidence that third party acted as defendant's agent with respect to the challenged statements); *Taylor v. Checkrite, Ltd.*, 627 F. Supp. 415, 416–17 (S.D. Ohio. 1986) ("central factor" in determining whether an agency relationship exists is the "right of control" vested in the principal.).

[24] Plaintiffs cite to three grants that Cephalon made to third parties. (Opp. at 13 n. 94, Exs. 92, 93, 95). But Cephalon had no control (editorial or otherwise) over materials published by these third parties. For example, the Unrestricted Educational Grant Agreement tied to Plaintiffs' Exhibit 92 states that APF "is ultimately responsible for exercising full control over the content of the materials [and] Cephalon and/or its agents shall not provide any scripting, targeting points for emphasis, or other activities designed to influence the materials' content." (Ex. 4, Unrestricted Educational Grant Agreement to APF, TEVA_MDL_A_03315373.) Even the grant requests provide that "Cephalon has not had

Even Plaintiffs' key third-party witness (Russell Portenoy) testified that he independently created all of his publications—free from any influence by the Teva Defendants.[25] (Mem. at 9.) Plaintiffs ignore this evidence. As summarized in Appendix A, Plaintiffs do not provide evidence that ***any*** of the few unbranded materials they cite were false or influenced any Ohio doctors.

Nor can Plaintiffs argue that Moving Defendants acted as part of some joint conspiracy or joint enterprise. The Opposition fails to put forth any such evidence, and, in other briefs, Plaintiffs cite entirely lawful conduct by Teva USA and Cephalon, like participation in trade associations, use of speakers, and general business operations.[26] Plaintiffs unsurprisingly fail to point to a single communication, email, or other document showing that Moving Defendants agreed to act in concert with anyone else, much less for the purpose of engaging in some unlawful conduct.

3. Plaintiffs Fail To Establish The Element Of Causation.

Even if Plaintiffs could show some false marketing in the Counties (they cannot), Plaintiffs offer no evidence that it caused any Ohio prescriber to write an inappropriate prescription for Actiq, Fentora, or any other opioid. (Mem. at 12–14.)

This is fatal to their claims. Plaintiffs cannot rely upon aggregate proof regarding all detailing by all Defendants to meet their causation burden.[27] They must show causation as to "each individual defendant."[28] Yet, Plaintiffs fail to offer any evidence showing that a single Ohio doctor

---

nor will it have involvement in content development." (Opp. Ex. 95). This is wholly consistent with Cephalon's long-existing policy that it cannot control or influence the content of independent third-party publications. *See, e.g.*, Ex. 5, Policy on Funding to Support Independent, Third-Party Educational or Scientific Meetings, TEVA_MDL_A_11892887 (Oct. 2004); V. Baldassano Dep. Responses, Ex. 1 ¶¶ 101–02.

[25] R. Portenoy Dep., ECF No. 1983-8, 469:22–470:25; *id.* 471:1–4; *id.* 475:17–476:9 (testifying that he was not influenced by others or asked to change or alter his views).

[26] ECF No. 2090, at 4–5 (participate in trade forum), 12–15 (use of speakers), 15–27 (funding of third-party organizations) 40 n. 230 (business operations). The conspiracy and RICO claims also fail for the many reasons expressed in the separate motion for summary judgment on these claims. (ECF No. 1930.)

[27] *See* Mfr. Defs.' Mem. of Law ISO Causation MSJ, ECF No. 1894, at 6–22.

[28] ECF No. 2099, at 3; *see also Sindelir v. R.J. Corman Const.*, No. 93-3042, 1993 WL 533119, at *3 (6th Cir. Dec. 23, 1993) (applying rule); *Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) (same).

was misled by an allegedly false statement made by any Moving Defendant, a single prescription was written as a result, or a single patient was harmed. None of Plaintiffs' experts addresses causation as to Moving Defendants. Nor can they, given that no marketing or causation expert identified a single false statement made by any Moving Defendant. (Mem. at 7 & n. 9.)

4. Plaintiffs Have Not Shown A Cognizable Injury Linked To Moving Defendants' Medicines.

Plaintiffs also have no evidence of a cognizable injury—that is, an Actiq or Fentora prescription that was harmful to a County resident, ineffective to treat the condition of any County resident, led to an overdose, or was otherwise diverted and caused harm to either County.[29] Nor do they offer any such evidence regarding any other opioid manufactured by any Moving Defendant. Plaintiffs' Opposition simply ignores these facts. Because they have not identified any evidence of any injury linked to Moving Defendants, summary judgment must be granted.[30]

B. The SOM Claims Fail For Lack Of Evidence As To The Key Elements.

Plaintiffs argue that Moving Defendants' internal SOM systems violated regulations under the Controlled Substances Act ("CSA"). (Opp. at 16–19.) But this is just one element of Plaintiffs' SOM claims. Plaintiffs also must prove causation and a cognizable injury. They offer no evidence to establish either. They have failed to come forward with evidence showing that: (a) a single suspicious order was filled by Moving Defendants, much less one that was ultimately shipped into the Counties; or (b) any harm caused by such a non-existent order. (Mem. at 15–17.) Because of these glaring failures, summary judgment must be granted.[31]

---

[29] Mem. at 3, 14–15.

[30] *See, e.g., Rugiero v. Nationstar Mortg., LLC*, 580 F. App'x 376, 378 (6th Cir. 2014) (failure to respond to arguments is basis for summary judgment); *Everson v. Leis*, 556 F.3d 484, 496 (6th Cir. 2009) (same).

[31] *See Zappola v. Hennig*, 20 F. Supp. 2d 1150, 1152 (N.D. Ohio 1998), aff'd sub nom. *Zappola v. Henning*, 201 F.3d 442 (6th Cir. 1999) ("To survive a motion for summary judgment, the non-movant must show there is evidence to support each element of his or her case.").

Simply put, if no suspicious orders were filled, then there was no causation or harm. Because Plaintiffs have failed to identify any suspicious orders that Moving Defendants should not have filled, there is no basis for a jury to find that Moving Defendants' shipments would have been any different if they had the SOM systems that Plaintiffs now demand. As such, there is no evidence that any allegedly inadequate SOM system caused any inappropriate opioid shipment to be made by any Moving Defendant into either County, or that such a shipment led to any harm.

Moreover, Plaintiffs are wrong about the alleged flaws of Moving Defendants' programs. There has never been any legal obligation to have a particular type of SOM system—DEA registrants are only required to have a system capable of identifying suspicious orders.[32] The applicable regulation states that the "registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances."[33] And the evidence is undisputed that Moving Defendants more than satisfied this obligation. They have always had controls in place to prevent diversion and have utilized SOM systems to identify, investigate, report, and hold suspicious orders.[34] Plaintiffs' attempt to invent new CSA requirements does not save their claims.

C. Plaintiffs Cannot Meet Their Burden Because They Have Chosen Not To Present Evidence Against Most Of Moving Defendants.

Plaintiffs fail to address the vast majority of Moving Defendants—all distinct corporate entities against whom Plaintiffs must prove their case. Plaintiffs, for instance, offer no evidence of wrongdoing by Teva Ltd., an Israeli company that never marketed, distributed, or manufactured opioids anywhere, much less in Ohio.[35] Nor do they provide any individualized evidence

[32] T. Prevoznik Dep., ECF No. 1893-9, 179:22-180:11 (agreeing that registrant has discretion to design system that works with its own business model and customer base); J. Rafalski Expert Report, ECF No. 1999-21 at 12–13 (recognizing that regulation only requires that registrant employ "some" SOM system).
[33] 21 C.F.R. § 1301.74(b).
[34] ECF No. 2159 at 28–34, 42–48; *Id.* Ex. 35, C. McGinn Decl. ¶¶ 8, 15; *Id.* Ex. 37, J. Tomkiewicz Decl. ¶ 16.
[35] In fact, Teva Ltd. is not subject to personal jurisdiction for the reasons set forth in its Motion to Dismiss. *See* Teva Ltd.'s Mot. to Dismiss (ECF No. 500); Mem. Ex. 56, H. West Decl. ¶¶ 6, 2–3.

regarding the eleven Actavis Generic Defendants.[36] At summary judgment, Plaintiffs cannot simply lump these entities together as "Teva" and conflate the alleged conduct of different entities at different times. They must prove wrongdoing by each entity they seek to hold liable.[37]

D. All Claims Are Barred By The Applicable Statute Of Limitations.

As Defendants have demonstrated, the applicable limitation period is October 2012 (at the latest).[38] Yet Plaintiffs cannot show any misconduct by any Moving Defendant ***after*** that time. With respect to their false marketing claims, the Opposition offers virtually no evidence of ***any marketing conduct*** after October 2012—other than the entirely lawful "Pain Matters" video and a few third-party publications that neither Teva USA nor Cephalon controlled. (Opp. at 13–15 ("2011-Forward" conduct).) Nor can Plaintiffs prove causation during the limitation period, given that the TIRF REMS program has required all prescribers and patients to acknowledge in writing the risks associated with Actiq and Fentora since March 2012. (Mem. at 6–7, 17.) This precludes any finding that Teva USA or Cephalon misled any Ohio prescriber or patient as to their brand products. And there is simply no evidence of any promotional statements about generic medicines.

Plaintiffs' SOM theory fails, too, because there is no evidence of any suspicious orders that Moving Defendants failed to report, investigate, or halt after October 2012. Plaintiffs further concede that Moving Defendants had systems in place and that they reported suspicious orders after October 2012. (*Id.* at 18.) The applicable statutes of limitation bars all claims. For this reason too, summary judgment is required.

---

[36] Plaintiffs refer to their affirmative summary judgment motion with respect to the Actavis Generic Defendants (Opp. at 19), but there too Plaintiffs fail to address these entities by name or offer any evidence whatsoever about their specific suspicious order monitoring practices or conduct.

[37] *See, e.g.*, *Brown v. Fred's, Inc.*, 494 F.3d 736, 739 (8th Cir. 2007) (affirming summary judgment as to parent company where plaintiffs failed to present sufficient evidence to create a genuine issue of fact for trial as to that entity); *Sindelir.*, 1993 WL 533119, at *3 (granting summary judgment where plaintiff failed to present "evidence of tortious conduct on the part of each defendant"); *see also Pang*, 559 N.E.2d at 1324 (same).

[38] Mfr. and Distributor Defs.' SOL Mem., ECF No. 1896 at 12–25, 32–39.

Dated: August 16, 2019

Respectfully submitted,

/s/ Steven A. Reed
Steven A. Reed
Eric W. Sitarchuk
Rebecca J. Hillyer
MORGAN, LEWIS & BOCKIUS LLP
1701 Market Street
Philadelphia, PA 19103-2921
Telephone: +1.215.963.5000
Facsimile: +1.215.963.5001
steven.reed@morganlewis.com
eric.sitarchuk@morganlewis.com
rebecca.hillyer@morganlewis.com

Nancy L. Patterson
MORGAN, LEWIS & BOCKIUS LLP
1000 Louisiana Street, Suite 4000
Houston, TX 77002-5005
Tel: (713) 890-5195
nancy.patterson@morganlewis.com

Brian M. Ercole
MORGAN, LEWIS & BOCKIUS LLP
200 S. Biscayne Blvd., Suite 5300
Miami, FL 33131-2339
Tel: (305) 415-3000
brian.ercole@morganlewis.com

Attorneys for Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc. f/k/a Watson Pharma, Inc., Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 16, 2019, the foregoing was filed using the Court's CM/ECF filing system and will be served via the Court's CM/ECF filing system on all attorneys of record.

/s/ *Steven A. Reed*
Steven A. Reed